

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

Rec'd PCT/PTO 22 JUL 2004

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DOCKETED

PCT

WRITTEN OPINION

(PCT Rule 66)

| | | |
|---|---|---|
| Applicant's or agent's file reference OSTEON332 | | Date of Mailing (day/month/year) 19 MAY 2004 |
| International application No. PCT/US03/01985 | | REPLY DUE within 1 months/days from the above date of mailing |
| International filing date (day/month/year) 22 January 2003 (22.01.2003) | Priority date (day/month/year) 23 January 2002 (23.01.2002) | |
| International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 6/08; C08K 3/18, 3/22, 3/40; C08F 222/38, 126/00 and US Cl.: 523/116; 524/430,494; 526/307,312 | | |
| Applicant UAB RESEARCH FOUNDATION | | |

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

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3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **23 May 2004 (23.05.2004)**

| | |
|---|---|
| Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | Authorized officer Tatyana Zalukaeva Telephone No. (571) 272-1700 |
|---|---|

REGISTRAR/PTO/AS
PATENT SPECIALIST

per

WRITTEN OPINION

International application No. _____

PCT/US03/01985

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 pages 1-37 _____, as originally filed
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____
- ☒ the claims:
 pages 38-42 _____, as originally filed
 pages NONE _____, as amended (together with any statement) under Article 19
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____
- ☒ the drawings:
 pages 1-7 _____, as originally filed
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages NONE _____, as originally filed
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE _____
- ☐ the claims, Nos. NONE _____
- ☐ the drawings, sheets/fig NONE _____

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.
PCT/US03/01985

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

| | | |
|-------------------------------|------------------------------------|-----|
| Novelty (N) | Claims 14-16,18-23,27-34,40 and 46 | YES |
| | Claims 1-3,17, 24-26, 35, 41, 42 | NO |
| Inventive Step (IS) | Claims NONE | YES |
| | Claims 1-42 | NO |
| Industrial Applicability (IA) | Claims 1-42 | YES |
| | Claims NONE | NO |

2. CITATIONS AND EXPLANATIONS

Claims 1-3,17,18, 20-26, 35, 41,42 lack novelty under PCT Article 33(2) as being anticipated by CULBERTSON et al (U.S. 5,369,142A).

CULBERTSON discloses glass ionomere cement composed of acryloyl and methacryloyl derivaticves of aminoacids (abstract). The polymers have pendent amino acid residues, specifically acrylic acid polymers or copolymers of acrylic acid, and itaconic acid, which are modified to contain to acryloyl or methacryloyl derivatives of amino acids. These materials provide water soluble polymers with pendent amino acid residues. In contrast to conventional, non-amino acid derivatized acrylic acid polymers and/or acrylic acid-itaconic acid copolymers, the polymers of the present invention produced by incorporation of the amino acid based monomers have some of the carboxylic acid residues removed at various spacer distances from the backbone of the parent polymer, with the spacer distance determined by the type of amino acid monomer used for the polymer synthesis. Polymers of this type also have pendent acid groups with a wider range of pKa values (col.2, lines 53-68).The particularly preferred monomers to produce the standard polyalkenoic acids are acrylic acid, itaconic acid and maleic acid, and the chlorides or anhydrides thereof (col.4, lines 24-26).

The synthetic and natural amino acids that can be used according to the present invention to modify the binder of a glass ionomer dental cement by forming the acryloyl or methacryloyl functionalized monomers for this invention include, but are not limited to, glycine, glycyglycine, alanine, valine, leucine, isoleucine, phenylalanine, tyrosine, proline, hydroxyproline, serine, threonine, 3-amino-3-methylbutanoic acid, 6-aminocaproic acid, aminobenzoic acid (meta and para), 4-aminosalicylic acid, iminodiacetic acid, lanthionine, methionine, aspartic acid, glutamic acid, lysine, delta-aminolevulinic acid, beta-alanine, alpha-aminobutyric acid, gamma-aminobutyric acid, gamma, epsilon-diaminopimelic acid, gamma, alpha-diaminobutyric acid, ornithine, omega-aminododecanoic acid, beta-cyanoalanine, epsilon-methylhistidine, canavanine, djenkoic acid, 1-azaserine, gamma-methylene glutamic acid, N-methyl tyrosine, arginine, tryptophan, norvaline, cystine, cysteine, and hydroxylysine (col.4, lines 28-45). See also col. 5, linesa 15-25 and schemes V and VI. Examples 12-17 provide for the synthsis of polymers as instantly claimed.

Claims 19, 27-34, 36-40 lack an inventive step under PCT Article 33(3) as being obvious over CULBERTSON. CULBERTSON is silent about specific species of HEMA, as per claim 19. However, it is obvious in light of generically taught functional acrylate monomers to include HEMA in order to impart hydroxyl functionality. CULBERTSON is silent about the use of reducing and oxidizing agents. However, the oxidizing agents are present in Culbertson, and it will be within the skilled artisan expectation to utilize both catalytical systems with the reasonable expectation of success.

Culbertson does not specifically recognize the use of a two package system, wherein a second package contains different ingredients of a glass ionomer composition. However, CULBERTSON suggests to apply separately and to keep separately a curable dental filling material comprising the polymers as claimed, and a separate reactive powder (see col.6, lines 20). Therefore those skilled in the art would have found obvious to maintain a composition as two package composition in order to avoid premature curing of a polymer, and will thus arrive at the instantly claimed subject matter.

Claims 1-42 meet the criteria set out in PCT Article 33(4), and thus the criteria for industrial applicability because the subject matter claimed can be made or used in industry as orthopaedic and dental cements.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.